(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number : **0 420 488 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication of patent specification : **21.07.93 Bulletin 93/29**

(51) Int. Cl.[5] : **A61M 25/10,** A61M 29/02, A61L 29/00

(21) Application number : **90310240.8**

(22) Date of filing : **19.09.90**

(54) Multilayer extrusion as process for making angioplasty balloons.

(30) Priority : **25.09.89 US 411649**

(43) Date of publication of application : **03.04.91 Bulletin 91/14**

(45) Publication of the grant of the patent : **21.07.93 Bulletin 93/29**

(84) Designated Contracting States : **AT BE CH DE DK ES FR GB GR IT LI LU NL SE**

(56) References cited :
EP-A- 0 214 721
EP-A- 0 274 411
DE-A- 2 635 785
US-A- 3 141 912
US-A- 4 608 984
US-A- 4 820 349

(73) Proprietor : **SCHNEIDER (USA) INC.,**
5905 Nathan Lane
Plymouth, Minnesota 55442 (US)

(72) Inventor : **Hamlin, Robert N.**
1317 North Broadway
Stillwater, Minnesota (US)

(74) Representative : **Bradbrook, Geoffrey William et al**
PFIZER LIMITED Ramsgate Road
Sandwich Kent, CT13 9NJ (GB)

EP 0 420 488 B1

Description

This invention relates generally to so-called balloon catheters, and more particularly to a method for fabricating a multi-layer balloon composite exhibiting enhanced characteristics attributable to the properties of the individual layers.

As an alternative to open-heart, coronary bypass surgery, a technique referred to coronary transluminal angioplasty has been developed following the pioneering introduction of the technique by A. Gruntzig. In carrying out this procedure, a dilatation catheter having an inflatable expander member (balloon) on the distal end thereof is routed through the vascular system to a location within a coronary artery containing a stenotic lesion. Following placement of the expander member across the lesion, a fluid is introduced into the proximal end of the catheter and is used to inflate the expander member to a predetermined relatively high pressure whereby the lesion is compressed into the vessel wall restoring patency to the previously occluded vessel.

It is desireable that the expander member exhibit the following characteristics:

1. High burst strength;
2. Low radial expansion at elevated pressures;
3. Ease of bonding to a catheter body;
4. Failure characteristics avoiding pinhole ruptures; and
5. Low coefficient of friction

The Schjeldahl et al Patent US-A-4,413,989 owned by applicants' assignee discloses a coronary transluminal angioplasty catheter in which the expander member is formed from polyethyylene terephthalate in a drawing and blow molding process so as to provide biaxial orientation to the material. Similar expander members are described in EP-A- 0 274 411 and US-A- 4.820.349. Such PET balloons are found to exhibit the desireable property of high burst strength and relatively low radial expansion when inflated to seven atmospheres or more. However, because the catheter body itself is generally fabricated from a formulation containing silicon rubber, polyethylene, PET or polyurethane, a problem exists when attempts are made to bond the expander member to the distal end portion of the catheter body. The PET polyester balloon tends not to adhere easily to the catheter body especially in a thermal bonding process.

Moreover, experience with polyethylene, PVC and polypropylene expansion members has shown that at relatively high pressures, pinhole leaks form which may create a high velocity jet of inflation fluid capable of perforating the blood vessel when it impinges on the vessel wall. Thus, it would be desirable if the expander member can be fabricated in such a way that it exhibits a controlled mode of failure, i.e., a rapid rupture so that the pressure is released over a significant area in a short time frame.

The above-listed desirable characteristics are achieved in accordance with the present invention by forming a multi-layer balloon where the individual layers afford a desirable property to the composite. More particularly, a tubular parison is first generated in a co-extrusion process whereby different polymeric materials are coaxially layered. Subsequently, the parison is inserted in a blow molding fixture, allowing the tube to be longitudinally drawn and radially expanded until the composite film is oriented, the maximum O.D. of the expander member is defined and a desired film thickness is achieved. For example, in forming the parison, PET of a predetermined viscosity may be coextruded and where polyethylene in forming the parison and where the polyethylene lines the lumen thereof. When the expander member is formed from the parison in the blow molding operation, the PET layer affords the desired burst strength and limited radial expansion characteristic while the polyethylene layer enhances the ability to bond the resulting balloon to the catheter body.

The characteristic of lubricity may also be added by coating the exterior of the composite with a suitable plastic exhibiting high hydrophilic characteristics. For example, the composite PET/polyethylene balloon may be coated on the exterior of the PET with polycaprolactam.

By forming a three-layer tubular parison where one of the layers is a plastic with known rupture characteristics, the polyethylene layer may provide the bondability attribute, the PET, the limited radial expansion characteristic and/or the controlled rupture characteristic while polycaprolactam again affords the lubricity.

The various features, characteristics and advantages of the invention will become apparent to those skilled in the art from the following detailed description of a preferred embodiment, especially when considered in conjunction with the accompanying drawings in which:

Figure 1 is a process flow chart illustrative of the present invention;

Figure 2 is a partial schematic illustration of apparatus for manufacturing parisons in co-extrusion process;

Figure 3 is a cross-sectional view of a two-component co-extrusion die useful in forming a two-layer parison;

Figure 4 illustrates schematically apparatus for blow molding the parison into a biaxially oriented multilayer expander member; and

Figure 5 shows the expander joined to the distal end of a catheter.

With reference to Figure 1, in fabricating the multilayer expander member in accordance with the present invention, the first step in the process is to create a parison which, when heated and then drawn

and blown creates a balloon or expander member for use on an intravascular catheter. The extruding apparatus is indicated generally by numeral 10 in Figure 2 and is seen to comprise a motor 12 coupled in driving relationship to a gear box 14 whose output shaft comprises a coarse-pitched archimedian screw 16 rotating within a heated barrel 18. In accordance with known practice, the screw generally has three distinct sections. In the "feed" section 20, directly beneath the feed hopper 22, the screw channel depth is constant and relatively large and serves to convey solid polymer material from the hopper. The depth of the flute in the "compression" section 24 is uniformly tapered and designed to compact the plastic and force it into contact with the barrel 18 to enhance melting. The melting is achieved mainly by a combination of heat conducted from electrical heating elements 26 contained in the barrel and the heat generated by the intense shearing in the molten layer formed between the barrel and the solid material. Numberal 28 identifies the "metering" section of the screw in which the flute depth is constant and relatively small. It controls the output from the extruder in terms of quantity, steadiness and homogeneity. Disposed at the end of the screw 16 is an extruder die 30 which, in the case of the present invention, provides for co-extrusion of at least two different plastics. The first plastic passing through extruder 10 combines with a second plastic exiting a substantially identical extruder shown schematically at 32 to create a concentrically layered tubular parison, the cross-section of which is seen in the view of Figure 4.

Figure 3 is a cross-sectional view taken through a two-port co-extrusion die. For example, the output from the metering section 28 of the extruder 10 may be fed into die port A in Figure 3 while that from the metering section of the screw of extruder 32 feeds port B. The molten plastic flows together to form a layer with the plastic entering port B surrounding the plastic entering port A. As the plastic is made to flow through the die, air is also introduced through the central bore 34 of the die 30 to prevent the collapse of the tubular shaped exudate.

In accordance with one aspect of the invention, the plastic entering port A, for example, may comprise a polyolefin or PVC while that forced into port B may be a homopolyester, preferably PET, of a predetermined viscosity. With these two constituents, the resulting tubular parison will have the PVC as the inner tubular layer and the PET as its outer layer. The thickness of the individual layers will be determined by the mass flow ratios provided by the respective extruders. The final diameter of the parison is determined by the size of the die exit opening, the total flow of material into ports A and B and the take-away or draw speed.

The balloon itself is fabricated in a blow molding operation wherein the parison 40 is inserted into the blow mold 42 as shown in Figure 4 and air or other suitable fluid is introduced through the port 44 at a predetermined pressure. The mold 42 has a cavity 46 corresponding to the desired size of the balloon to be produced.

After the tubular parison is disposed in the mold, the mold is heated to thereby raise the tubing temperature to a point between the second order transition temperature and the first order transition temperature of the polyester polymer.

By first drawing the tubular parison and subsequently blow molding same, biaxial orientation takes place whereby the PET layer, while remaining flexible, become strong as regards the inflation pressure at which the material will burst. When it is desired to bond the finished balloon onto the catheter body as illustrated in Figure 5, the inner layer 48 of PVC can readily be bonded to an outer PVC tubular body 50 and to an inner tubular body 52. The space between the coaxially disposed tubes allows for injection of a balloon inflation fluid. Balloons produced in accordance with the invention may exhibit a burst pressure well in excess of 7 atmospheres while radially expanding less than about 3-10 percent. While the PVC layer 48 adds little to the burst strength of the composite, it does facilitate the attachment of the balloon to the exterior of the tubular catheter body.

If it is desired to increase the lubricity of the composite balloon, this may be accomplished by dipping or other coating the multilayer balloon in a suitable hydrophilic material such as polyvinylidol, N-vinylpyrolodone, hydrogels, etc.

Rather than utilizing PET in combination with PVC, a balloon having enhanced properties may be created by co-extruding a high molecular weight crystalline polyester with a lower molecular weight amorphous polyester in forming the parison. Following drawing and radial expansion in a blow molding operation, the resulting balloon is found to exhibit high burst strength, low radial expansion and superior bondability as compared to conventional PET single-layer balloons.

The rupture characteristics of a polymer layer can be modified to increase the rupture rate by adding filler material. The filler materials may be an inert type, such as calcium carbonate, generally in powder form, carbon in fiber form, or an incompatible second phase polymer. Incompatible phase polymer systems afford many advantageous characteristics and are a function of the dispersion between the two phases. Materials which might be candidates for this are polypropylene and selected rubbers, polyester and polypropylene.

This invention has been described herein in considerable detail in order to comply with the Patent Statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use such specialized components as

are required. However, it is to be understood that the invention can be carried out by specifically different equipment and devices, and that various modifications, both as to the equipment details and operating procedures, can be accomplished without departing from the scope of the invention itself.

Claims

1. An expander member for attachment to a medical catheter comprising:
   (a) an outer biaxially-oriented tubular polymeric film layer (40) exhibiting relatively high polymer crystallinity; and
   (b) an inner polymeric plastic film layer (48) adhered to said outer layer (40) and exhibiting relatively low polymer crystallinity.

2. The expander member of Claim 1 wherein said outer film layer (40) comprises polyethylene terephthalate co-polyester or homopolyester exhibiting a burst pressure in excess of seven atmospheres.

3. The expander as in Claim 2 wherein said inner film layer (48) comprises an amorphous polyester.

4. The expander as in Claim 2 wherein said inner layer (48) comprises a polyolefin.

5. The expander as in Claim 4 and further including a hot-melt adhesive disposed between said outer layer (40) and said inner layer (48).

6. The expander as in Claim 1 wherein said outer layer (40) is coated with a hydrophilic polymer.

7. The expander as in Claim 6 wherein said hydrophilic polymer is polycaprolatom.

8. Process for forming the expander member according to claims 1 to 7 for attachment to an intravascular catheter body member comprising the steps of:
   (a) co-extruding a polyester plastic exhibiting high polymer crystallinity with a polymeric material exhibiting low polymer crystallinity to form a layered tubular parison with said polymeric material exhibiting low polymer crystallinity on the interior of said tubular parison;
   (b) heating said parison in a mold to a predetermined temperature;
   (c) drawing said parison longitudinally and radially expanding same to biaxially orient said polyester exhibiting high polymer crystallinity such that said expander member exhibits a burst strength greater than about seven atmospheres.

9. The method as in Claim 8 wherein said polyester plastic is polyethylene terephthalate and said polymeric material is selected from the class including polyethylene, urethane and amorphous polyethylene terephthalate.

10. The method as in Claim 8 and further including the steps of:
    (d) coating said expander member with a hydrophilic plastic.

Patentansprüche

1. Expanderelement zur Befestigung an einem medizinischen Katheter, umfassend:
   (a) eine äußere biaxial orientierte schlauchförmige polymere Filmschicht (40), die eine relativ hohe Polymerkristallinität aufweist und
   (b) eine innere polymere Kunststoffilmschicht (48), die an der äußeren Schicht (40) befestigt ist und eine relativ niedrige Polymerkristallinität aufweist.

2. Expanderelement nach Anspruch 1, wobei die äußere Filmschicht (40) Polyethylenterephthalatcopolyester oder - homopolyester mit einem Reißdruck von mehr als 7 Atmosphären umfaßt.

3. Expander nach Anspruch 2, wobei die innere Filmschicht (48) einen amorphen Polyester umfaßt.

4. Expander nach Anspruch 2, wobei die innere Schicht (48) ein Polyolefin umfaßt.

5. Expander nach Anspruch 4, des weiteren umfassend einen heißgeschmolzenen Klebstoff, der zwischen der äußeren Schicht (40) und der inneren Schicht (48) angeordnet ist.

6. Expander nach Anspruch 1, wobei die äußere Schicht (40) mit einem hydrophilen Polymer beschichtet ist.

7. Expander nach Anspruch 6, wobei das äußere hydrophile Polymer aus Polycaprolactom besteht.

8. Verfahren zur Ausbildung des Expanderelements nach Anspruch 1 bis 7 zur Befestigung an einem intravaskulären Katheterkörperelement, umfassend die Schritte:
   (a) Coextrudieren eines eine hohe Polymerkristallinität aufweisenden Polyesterkunst-

stoffs mit einem niedrige Polymerkristallinität aufweisenden polymeren Material unter Bildung eines schichtförmigen schlauchartigen Külbels, wobei das polymere Material eine niedrige Polymerkristallinität auf der Innenseite des schlauchförmigen Külbels aufweist;
(b) Erwärmen des Külbels in einer Form auf eine vorbestimmte Temperatur;
(c) Streckziehen des Külbels in Längsrichtung und radiales Expandieren desselben, um den hohe Polymerkristallinität aufweisenden Polyester biaxial zu orientieren, so daß das Expanderelement eine Reißfestigkeit (bis zu einem Druck) von mehr als etwa 7 Atmosphären aufweist.

9. Verfahren nach Anspruch 8, wobei der Polyesterkunststoff aus Polyethylenterephthalat und das polymere Material aus der Klasse Polyethylen, Urethan und amorphes Polyethylenterephthalat ausgewählt ist.

10. Verfahren nach Anspruch 8, des weiteren umfassend den Schritt:
(d) Beschichten des Expanderelements mit einem hydrophilen Kunststoff.

Revendications

1. Elément expanseur destiné à être attaché à un cathéter médical comportant :
(a) une couche extérieure (40) formée d'un film polymérique tubulaire à orientation biaxiale présentant une cristallinité de polymère relativement élevée ; et
(b) une couche intérieure (48) d'un film de matière plastique polymérique adhérant à ladite couche extérieure (40) et présentant une cristallinité de polymère relativement basse.

2. Elément expanseur selon la revendication 1, dans lequel ladite couche de film extérieur (40) comprend un copolyester ou homopolyester de téréphtalate de polyéthylène présentant une pression d'éclatement supérieure à sept atmosphères.

3. Expanseur selon la revendication 2 dans lequel ladite couche de film intérieur (48) comprend un polyester amorphe.

4. Expanseur selon la revendication 2, dans lequel ladite couche intérieure (48) comprend une polyoléfine.

5. Expanseur selon la revendication 4 et comprenant en outre un adhésif thermofusible disposé entre ladite couche extérieure (40) et ladite couche intérieure (48).

6. Expanseur selon la revendication 1, dans lequel ladite couche extérieure (40) est revêtue d'un polymère hydrophile.

7. Expanseur selon la revendication 6, dans lequel ledit polymère hydrophile est un polycaprolactame.

8. Procédé pour former l'élément expanseur selon les revendications 1 à 7 devant être attaché à un élément de corps de cathéter intravasculaire, comprenant les étapes qui consistent :
(a) à coextruder une matière plastique du type polyester présentant une cristallinité de polymère élevée avec une matière polymérique présentant une cristallinité de polymère basse pour former une ébauche tubulaire à couches avec ladite matière polymérique présentant une cristallinité de polymère basse sur l'intérieur de ladite ébauche tubulaire ;
(b) à chauffer ladite ébauche dans un moule à une température prédéterminée ;
(c) à étirer ladite ébauche longitudinalement et à l'expanser radialement pour orienter biaxialement ledit polyester présentant une cristallinité de polymère élevée afin que ledit élément expanseur présente une résistance à l'éclatement supérieure à environ sept atmosphères.

9. Procédé selon la revendication 8, dans lequel ladite matière plastique du type polyester est un téréphtalate de polyéthylène et ladite matière polymérique est choisie dans la classe comprenant un polyéthylène, un uréthanne et du téréphtalate de polyéthylène amorphe.

10. Procédé selon la revendication 8 et comprenant en outre l'étape qui consiste :
(d) à revêtir ledit élément expanseur d'une matière plastique hydrophile.

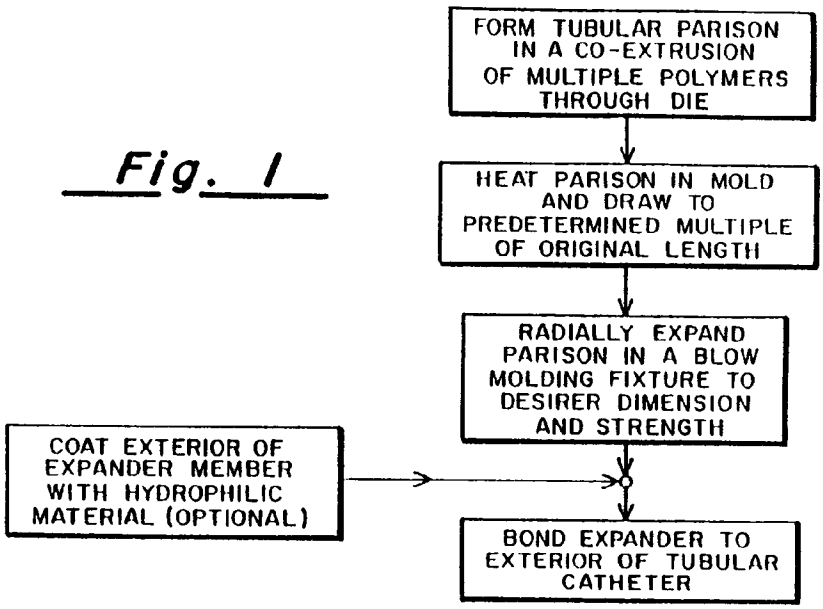

Fig. 1

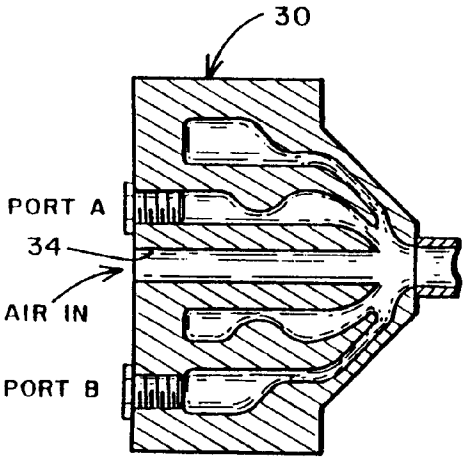

Fig. 3

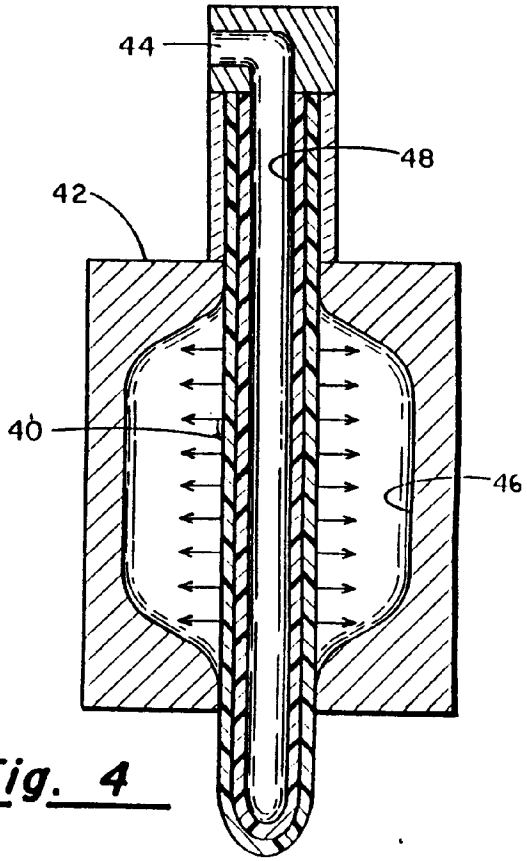

Fig. 4

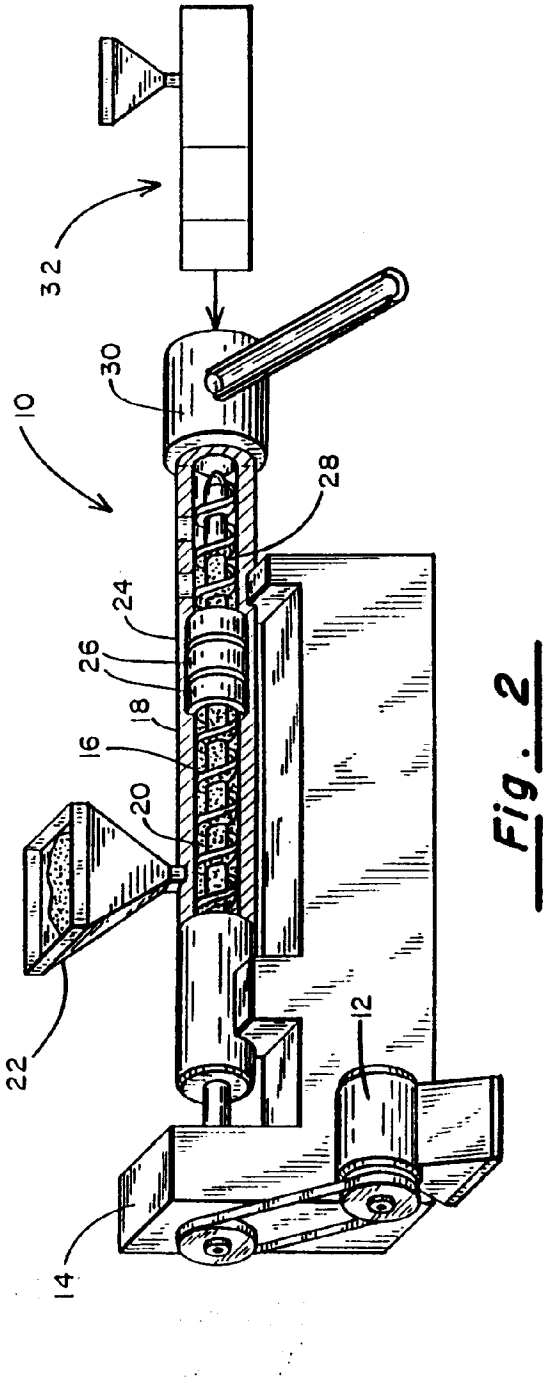

Fig. 2

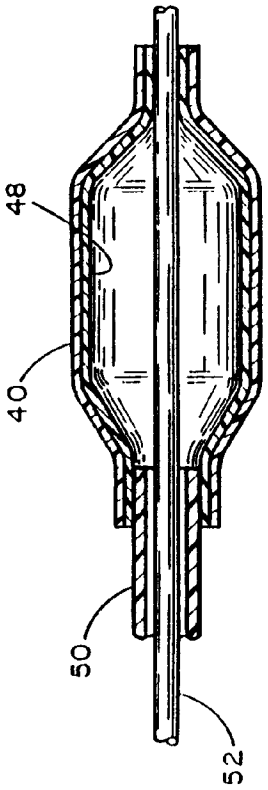

Fig. 5